

REMARKS

Claims 1 – 20 are currently pending. Claims 1, 15, and 20 are the pending independent claims. In the Office Action, the Examiner finally rejected Claim 1, 2, and 5 as allegedly being obvious in view of U.S. Patent No. 7,037,523 to Hussain et al. (“Hussain”) taken alone. In addition, Claims 3 and 4 were finally rejected as being obvious over Hussain in view of U.S. Patent No. 6,010,718 to Al-Razzak et al. (“Al-Razzak”).

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

As originally filed, Claims 1, 15, and 20 called for, *inter alia*, at least one pharmaceutically acceptable hydrophilic polymer in specifically defined amounts and with specific characteristics, including a relatively low viscosity. To the extent, if any, that it was not clear from the original claim language, Claims 1, 15, and 20 have been amended herein to specify that the pharmaceutically acceptable, relatively low viscosity polymer is both hydrophilic and water-soluble. However, Applicants do not believe it is necessary as a practical matter or for purposes of claiming their invention in compliance with §112 to add the redundancy of the characteristic or property “water-soluble” to “hydrophilic.” As is apparent from the specification, Applicants intended by use of the term “hydrophilic” to designate polymers that are water-soluble.

Turning now to the art rejection based on Hussain, Applicants respectfully submit that Hussain does not suggest a water-soluble form of the composition as claimed. In fact, Hussain is the antithesis of the claimed composition and as such, cannot reasonably be said to suggest the composition according to the law. Hussain is directed to pharmaceutical compositions which are based on the use of water insoluble polymers such as ethyl cellulose. *See, e.g.*, Hussain, Col. 4, lines 30 – 33 and Col. 5, lines 39 – 47. In stark contrast to the invention claimed by Applicants, the entire point of Hussain is to avoid the use of hydrophilic, water-soluble polymers in a pharmaceutical composition. According to Hussain, the processing of compositions containing such polymers “is difficult.” *See*, Hussain, Col. 2, lines 47 – 49.

The orientation of Hussain is therefore away from the direction taken by Applicants as defined in claims 1, 15, and 20. As such, Hussain cannot reasonably be said to “suggest” or otherwise make “obvious” the subject matter of these claims. A reference which criticizes the

use of hydrophilic or water-soluble ingredients in pharmaceutical compositions as inferior and problematic cannot reasonably be said to make a novel composition containing a major amount of a hydrophilic or water-soluble component obvious. Such is the very opposite of obviousness.

In the recent *KSR* decision, the Supreme Court reiterated the importance of “teaching away” as indicative of patentability in the course of explaining its earlier *Adams* opinion (a part of the *Graham* trilogy).

In *United States v. Adams*, 383 U.S. 39, 40, 86 S.Ct. 708, 15 L.Ed.2d 572 (1966), a companion case to *Graham*, the Court considered the obviousness of a “wet battery” that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. 383 U.S., at 50-51, 86 S.Ct. 708. It nevertheless rejected the Government’s claim that Adams’s battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51-52, 86 S.Ct. 708. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams’s design was not obvious to those skilled in the art.

KSR Intern. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1739 – 1740 (2007).

This reasoning is directly applicable here. Hussain would lead persons of ordinary skill in a direction opposite the direction pursued by Applicants. The claims therefore patentably distinguish over Hussain. All Section 103 rejections based on Hussain should be withdrawn.

The rejections of Claims 3 and 4 based upon the purported combination of Hussain with Al-Razzak, fail for similar reasons. The Examiner imagines that it would have been obvious to substitute the hydroxypropylmethyl cellulose polymer disclosed in Al-Razzak for the water-insoluble polymers disclosed in Hussain. However, intertwining these references in this way cannot reasonably be said to have been obvious. Viewed objectively with no knowledge of Applicant’s invention, a person of ordinary skill would see one reference (Al-Razzak) making reference to the use of relatively low amount of relatively high viscosity polymer materials said to be hydrophilic and another reference (Hussain) specifically deriding the use of hydrophilic polymers in pharmaceutical compositions. It would not be “obvious” to a person of ordinary skill to even attempt to combine such divergent references, but even if he/she did try to

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combine them, they still would not provide Applicants' claimed composition containing a relatively large amount of relatively low viscosity polymeric materials for the provision of a novel, effective extended release pharmaceutical composition. Again, as noted above, the specific intent of Hussain is to avoid the use of any water soluble or hydrophilic polymeric material in a pharmaceutical composition. Since Hussain teaches directly away from the use of a water-soluble or hydrophilic polymeric material in a pharmaceutical composition, the teachings of Hussain and Al-Razzak are plainly at odds with one another, and could not be "obviously" combined so as to suggest the subject matter of Claims 3 and 4.

In light of the foregoing, the present amendment is believed to place the application in a condition for allowance and entry of the foregoing amendments and allowance of Claims 1 - 26 is respectfully solicited.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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